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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,879	01/18/2000	Vernon L. Alvarez		1229

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 07/15/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action SummaryApplication No.
09/484,879Applicant(s)
Alvarez, V.L.Examiner
Bennett CelsaArt Unit
1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6, 8, 10, 13, 15-17, 19, 21, 23, 24, 27, 30, 33, 35, 36, and is/are pending in the application.
- 4a) Of the above, claim(s) 13, 15-17, 19, 21, 23, 24, 33, 35, 43, 44, and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6, 8, 10, 27, 30, 36, and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

Claims 2-4, 6, 8, 10, 13, 15-17, 19, 21, 23-24, 27, 30, 33, 35, 36, 40 and 43-46 are pending.

Claims 2-4, 6, 8, 10, 27, 30, 36 and 45 are under consideration.

Claims 13, 15-17, 19, 21, 23-24, 33, 35, 40, 43-44 and 46 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restriction

1. Applicant's election with traverse of Group I (claims 2-4, 6, 8, 10, 27, 30, 36 and 45) in Paper No. 10 is acknowledged.

First applicant argues that there is no serious burden to search Groups II and III in addition to Group I. This is not found persuasive for all the reasons provided in the reasons for restriction/election (e.g. See prior office action; items 5, 6, 7, and 8). As pointed out in the prior office action, these different groups have different classifications, require different and separately burdensome manual/computer searches and have divergent subject matter.

Applicant next argues that Groups I, IV, V, VII, VIII, IX, X and XI should be examined together since these groups are all directed to "Abtides". This is not found persuasive for all the reasons provided in the reasons for restriction/election (e.g. See prior office action; items 3, 7, and 8). As pointed out in the prior office action, these inventions are drawn to independent and/or patentably distinct compounds which require different and separately burdensome manual/computer structure, bibliographic and classification searches.

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Applicant further argues that Groups II, III and VI should be together, since these groups are all directed to methods of identifying and using "Abtides". This is not found persuasive for the reasons provided in the reasons for restriction/election (e.g. See prior office action; items 4. and 8). As pointed out in the prior office action, these groups are drawn to independent and/or patentably distinct methods since they have different method objectives, method steps, use different reagents and/or require different and separately burdensome manual/computer classification and bibliographic searches.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 2-4, 6, 8, 10, 27, 30, 36 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "molecule" is non-statutory.

Amending to claim "A compound" will overcome this rejection..

Claim Rejections - 35 USC § 112

4. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "is capable of binding to a human tumor antigen" is not definite as to whether the "antibody or antigen-binding derivative thereof" must currently bind a human tumor

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antigen or can somehow be derivatized to be made capable. If the latter, than the means of derivatizing is indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 2-4, 6, 8, 10, 27, 30, 36 and 45 are rejected under 35 U.S.C. 102(a,b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Griffiths et al. WO 93/11236 (6/93).

Present claims 2-4, 6, 8, 10, 27, 30, 36 and 45 are drawn to "product by process claims" which define the product solely by its method of making (e.g. screening). See MPEP 2113 directed to "Product by Process Claims". Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then

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obtain prior art products and make physical comparisons therewith." *In re Brown*, 173 USPQ 685, 688 (CCPA 1972)

The present claims (claims 2-4, 6, 8, 10, 27, 30, 36) are directed to "a peptide which mimics the binding specificity of an antibody" and which may be "capable of specifically binding to a human tumor antigen" as a result of the use in the method of "an antibody or antigen-binding derivative thereof which is capable of specifically binding to a tumor antigen" (e.g. see claim 45).

Griffiths disclose peptides which are "anti-self antibody fragments" (e.g. scFv, Fd, Fab or any other fragment which has the capability of binding antigen) which bind "self antigens". Accordingly, the Griffith antibody peptide fragments are "molecules comprising a peptide which mimics the binding specificity of an antibody" since the fragments mimic the ability of the parent antibody (monoclonal/polyclonal) to bind the same antigen (e.g. see abstract; examples and claims).

To the extent that patentable weight is given the limitation "capable of specifically binding to a human tumor antigen" due to the product-by process format and the use of "capable of"; the reference antibody fragments, nevertheless anticipate, since these peptides can be made "capable of specifically binding to a human tumor antigen" if the phage library is screened against a tumor antigen; or if the peptide is derivatized to enable tumor binding (e.g. conjugated to antibody that targets a tumor antigen). Additionally, since not all tumor antigens are known, the ability of a particular reference peptide to bind or not bind a tumor cell can only be determined through assaying each of the reference peptides; since any one of the reference peptides may possess the

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inherent ability to bind a tumor cell via an antigen to some degree. Accordingly, all of the reference screened peptides are potentially "capable of binding a human tumor antigen" to some degree; the degree of which must be determined by screening.

Further, the reference teaches the making of anti CEA (human) scFv antibodies (e.g. see pages 46-49, lines page 75 and Table 1) . Since human carcinoembryonic antigen (CEA) is "a human tumor antigen" the reference teaches a peptide (e.g. scFV antibody) which specifically binds (e.g. and therefore is capable of binding) a human tumor antigen (human CEA); and which also mimics the binding specificity of an antibody (e.g. an anti-CEA monoclonal or polyclonal antibody) and thus anticipates claims 2-4, 6, 8, 10, 27, 30, 36 as well as claim 45.

Background Document

Cruse et al. "Illustrated Dictionary of Immunology" (CRC Press 1994) page 51 and definition of "carcinoembryonic antigen (CEA)".

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

July 11, 2002

BENNETT CELSA
PRIMARY EXAMINER

